

NKTR-102 Demonstrates Significant Efficacy as Single-Agent in Second- or Third-Line Treatment in Metastatic Breast Cancer Patients

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SAN ANTONIO, and SAN FRANCISCO, Dec. 12, 2010 /PRNewswire-FirstCall/ -- Nektar Therapeutics (Nasdaq: [NKTR](#) [1]) today announced positive results from a Phase 2 clinical study evaluating single-agent NKTR-102 in patients with metastatic breast cancer during the 33rd Annual CTSC-AACR San Antonio Breast Cancer Symposium (SABCS). NKTR-102, a novel investigational topoisomerase I inhibitor-polymer conjugate, is Nektar's lead oncology candidate and is being evaluated in multiple cancer indications. The randomized Simon two-stage study presented at SABCS evaluated two 145 mg/m² dose schedules of single-agent NKTR-102, every two weeks (q14d) and every three weeks (q21d), in 70 metastatic breast cancer patients who failed a prior taxane therapy. Eighty-seven percent (61/70) of patients in the study received a prior anthracycline/taxane with or without capecitabine.

More than one million women worldwide are diagnosed with breast cancer every year and anywhere from 30% to 80% develop metastatic disease.(1)

A total of 66 of the 70 patients treated in the Phase 2 study were assessable for the primary endpoint of objective tumor response rate (ORR), including confirmed complete and partial responses per RECIST. As of October 26, 2010, confirmed ORR for all evaluable patients was 32% (10/31) for the q14d schedule and 26% (9/35) for the q21d schedule, including two confirmed complete responses (CRs) on the q14d schedule. An additional four patients had near CRs, with 100% disappearance of all target lesions. The combined ORR for all evaluable patients was 29% (19/66).

Clinical benefit rate for the 66 evaluable patients was 41% (defined as CR+PR+SD greater than or equal to 6 mos).

"These are important new results for NKTR-102 in patients with metastatic breast cancer," said Prof. Ahmad Awada, Head of the Medical Oncology Clinic

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